RWANDA FDA
Rwanda Food and Drugs Authority

GUIDELINES FOR REVIEW AND APPROVAL OF CLINICAL TRIALS

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FOREWORD

Rwanda Food and Drugs Authority (Rwanda FDA) is a regulatory body established by Law N° 003/2018 of 09/02/2018, specifically in article 8, paragraph 7 and 12 with a mandate to regulate and inspect clinical trials in Rwanda. Reference is made to the provisions of the technical regulation N° DD/PVCT/TGR/001 Version 4 governing the conduct of clinical trials, the Authority issues Guidelines *N° DD/PVCT/GDL/008 Version 3* for review and approval of clinical trials.

These guidelines have been developed to provide a model of review of clinical trials to ensure compliance with sound scientific aspects and regulatory requirements prior to approval and authorization by the Authority.

These guidelines were developed in reference to the existing guidelines of the World Health Organization (WHO) and the International Conference on Harmonization of Technical Requirements for Good Clinical Practices (ICH E6) and other available literature.

The Authority acknowledges all the efforts of key stakeholders who participated in the development and validation of these guidelines.

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Director General

DOCUMENT DEVELOPMENT HISTORY

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Document Revision History

Date of revision	Version number	Changes made and/or reasons for revision
16/07/2021	1	First issue
03/04/2023	2	1. The reference number was changed from DIS/GDL/042 to No FDISM/PVSM/GDL/001 Rev_2 as per the current SOP on document control 2. Timelines for review during emergencies was revised as per AVAREF recommendations; 3. Components on review of safety handling were removed; 4. Criteria for accepting GMPs for imported IPs were included; 5. Statement for review by the technical committee was included; 6. Templates of the AVAREF were adopted; 7. Necessary editorial changes in line with SOP on document control were included.
	3	1. Rolling review of benefit-risk was added to the section 3.4.2 Non-routine reviews of clinical trial application 2. Provisions for submission of new clinical trial application when new data require significant changes, were included to the section 3.5 Review of additional data & updates on clinical Applications 3. Provisions for review of clinical investigations on medical devices, In vitro-Diagnostics and software were added to the section 3.6.3 Review of Clinical Data 4. Section 5.3 Publication of clinical trials evaluation reports was included; 5. Relocating the appendices, as reviewers and stakeholders can access them separately through alternative channels 6. Necessary editorial changes in line with SOP on document control were included.

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ACCRONYMS AND ABBREVIATIONS

AE:	Adverse Event
API:	Active pharmaceutical Product
AVAREF:	African Vaccine Regulatory Forum
CIOMS:	Council of International Organization for Medical Science
CRO:	Contract Research Organization
CRF:	Case report form
CTA:	Clinical Trial Application
CTA-A:	Clinical Trial Application for Amendment
EUAL:	Emergency Use Assessment and Listing Procedure
GMP:	Good Manufacturing Practice
ICH:	International Conference on Harmonization
ICFs:	Informed Consent Forms
IRB:	Institutional Review Board
MTA:	Material Transfer Agreement
NDA:	New Drug Application
PI:	Principal Investigator
RNEC:	Rwanda National Research Ethics Committee
Rwanda FDA	Rwanda Food and Drugs Authority

GLOSSARY / DEFINITIONS

In these Guidelines, unless the context otherwise states:
"An applicant'' means the Sponsor or Principal Investigator. The applicant shall therefore be responsible for signing the application form.

"Authority" Means Rwanda Food and Drugs Authority or its acronym "Rwanda FDA", established by the Law No 003/2018 of 09/02/2018.

"Amendment" A written description of a change(s) to or formal clarification of a protocol.

"Applicable Regulatory Requirement(s)" Any law(s) and regulation(s) addressing the conduct of clinical trials of investigational products.

"Blinding/Masking" A procedure in which one or more parties to the trial are kept unaware of the treatment assignment(s). Single-blinding usually refers to the participant(s) being unaware; and double-blinding usually refers to the participant(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s).

"Child" A person who is below eighteen (18) years of age or the definition of child as defined in the laws currently enforced in Rwanda.

"Case Report Form" A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each study participant.

"Clinical Trial" Any investigation in human study participants intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

"Clinical Trial Report" A written description of a trial/ study of any therapeutic, prophylactic or diagnostic agent conducted in human study participants in which the clinical and statistical description, presentations and analyses are fully integrated into a single report.

"Data and Safety Monitoring Board" An independent data monitoring committee that may be established by the sponsor to assess at intervals the progress of a clinical trial, the safety data and the critical efficacy endpoints and to recommend to the sponsor whether to continue, modify, or stop a trial.

"Documentation" All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and electrocardiograms) that describe or record the methods, conduct, and/or results of a trial, the factors affecting a trial, and the actions taken.

"Essential Documents" Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.

"Ethical Clearance" An authorization to conduct a clinical trial issued by the Rwanda National Research Ethics Committee (RNEC) or Institutional Review Boards (IRB) based on ethical issues related to trials involving human participants in Rwanda.

"Good Clinical Practice" A standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial/study participants are protected.

"Good Manufacturing Practice (GMP)" The part of pharmaceutical quality assurance which ensures that products are consistently produced and controlled to quality standards appropriate to their intended use and as required by the marketing authorization.

"Impartial witness" A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the Informed Consent Form and any other written information supplied to the participant.

"Informed Consent" A process by which a study participant voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the study participant's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form.

"Investigational Product" A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use.

"Investigator" A physician, dentist or other qualified person who conducts a clinical trial at a trial site. See also Sub-investigator.

"Investigator's Brochure" A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human study participants.

"Legal representative" The name given to describe the executor, administrator or the person who looks after another person's affairs.

"Materials Transfer Agreement" An MTA is a written contract that governs the transfer of tangible research materials or biological samples between parties.

"Multi-centre Trial" A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

"Phase I trials" These are first trials of a new active ingredient or new formulations in man, often carried out in healthy volunteers. Their purpose is to establish a preliminary evaluation of safety, and a first outline of the pharmacokinetic and, where possible, a pharmacodynamic profile of the active ingredient in human.

"Phase II trials" These trials are performed in a limited number of study participants and are often, at a later stage, of a comparative (e.g. placebo-controlled) design. Their purpose is to demonstrate therapeutic activity and to assess short-term safety of the active ingredient in patients suffering from a disease or condition for which the active ingredient is intended. This phase also aims at the determination of appropriate dose ranges or regimens and (if possible) clarification of dose-response relationships in order to provide an optimal background for the design of extensive therapeutic trials.

"Phase III trials" Trials in larger (and possibly varied) patient groups with the purpose of determining the short and long-term safety/efficacy balance of formulation(s) of the active ingredient, and of assessing its overall and relative therapeutic value. The pattern and profile of any frequent adverse reactions must be investigated and special features of the product must be explored (e.g. clinically-relevant investigation medicinal product interactions, factors leading to differences in effect such as age). These trials should preferably be of a randomized double-blind design, but other designs may be acceptable, e.g. long-term safety studies. Generally, the conditions under which these trials are carried out should be as close as possible to normal conditions of use.

"Phase IV studies" Studies performed after marketing of the pharmaceutical product. Trials in phase IV are carried out on the basis of the product characteristics on which the marketing authorization was granted and are normally in the form of post-marketing surveillance, or assessment of therapeutic value or treatment strategies. Although methods may differ, these studies should use the same scientific and ethical standards as applied in pre-marketing studies. After a product has been placed on the market, clinical trials designed to explore new indications, new methods of administration or new combinations, etc. are normally considered as trials for new pharmaceutical products.

"Placebo" An inactive substance or sham form of a therapy administered as a control in testing experimentally or clinically the efficacy of a biologically active preparation or procedure.

"Pre-clinical Studies" Biomedical studies not performed on human study participants.

"Principal Investigator" A person responsible for the conduct of the clinical trial at a trial site who is a physician, dentist or other qualified person, resident in Rwanda and a member of good standing of a professional body. If a trial is conducted by a team of individuals at a trial site, the principal investigator is the responsible leader of the team. See also Sub-investigator.

"Protocol" A document that describes the objective(s), design, methodology, statistical considerations and organization of a trial. The protocol usually also gives the background and rationale for the trial but these could be provided in other protocol referenced documents.
"Protocol Amendment" A written description of change(s) to or formal clarification of a protocol.

"Randomization" The process of assigning trial study participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.

"Source Data" All information in original records and certified copies of original records of clinical findings, observations or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents (original records or certified copies).

"Sponsor" An individual, company, institution or organization which takes responsibility for the initiation, management and/or financing of a clinical trial.

"Standard Operating Procedures (SOP)" Detailed written instructions to achieve uniformity of the performance of a specific function.

"Substantial amendment": means change to the terms of the protocol or any other trial supporting documentation that is likely to have significant impact and affect the safety and integrity of trial participants, the scientific value of the research, the conduct or management of the research, and the quality or safety of any investigational medicinal product used in research.

"Trial Site" The location(s) where trial-related activities are actually conducted.

CHAPTER ONE: INTRODUCTION

Clinical trials are planned scientific investigations conducted on humans and animals to gather information on safety and efficacy of medical products and health technologies. Such experiments involve the administration of investigational products in patients, healthy volunteers or animal species to generate data that can later be used for marketing authorization of a product.

These guidelines highlight the clinical trial review process of submitted data to the Rwanda FDA for further authorization to conduct clinical trials in Rwanda ensuring compliance with Good Clinical Practice (GCP) principles and regulatory requirements.

I.1 SCOPE

These guidelines apply to the review of all scientific aspects and regulatory requirements for clinical trial applications.

These guidelines cover the review of Clinical Trial Application (CTA) of both unregistered or registered investigational products which include pharmaceutical products, vaccines and other biological products, herbal medicines, cosmetics, medical devices and in vitro diagnostics with new intended uses.

CHAPTER II: REVIEW OF CLINICAL TRIAL APPLICATIONS

The CTAs submitted to Rwanda FDA are not considered valid until they have been screened for completeness. All applications for clinical trial conduct in Rwanda shall undergo screening and full assessment with exception of applications submitted using reliance pathways which may be waived from full assessment. In this case, the review process shall focus on regulatory requirements, review reports and decisions from other regulatory authorities or joint reviews.

II.1 Screening of Clinical Trial applications

On receipt of CTAs the Rwanda FDA shall assign the reference number to the application which will be communicated with applicant for future correspondences.

The application shall then be screened for completeness and compliance with the regulatory requirements **within ten (10) working days** from the submission date.

During the screening of CTAs, the Rwanda FDA shall record all required information related to the application using screening checklist prescribed in the corresponding standard operating procedures (SOP) and electronic system with a screening report generated.

The Clinical Trial Applications shall pass the screening stage and be accepted for review if more than 70% of the applicable requirements are provided. This shall include but not be limited to the signed, dated application letter and forms, duly signed protocol, updated Investigator's Brochure, proof of payment of applicable fees, declarations and agreement between the sponsor and principal investigator.

In case the applicant has provided incomplete information after screening, the Rwanda FDA communicates in writing and request missing regulatory requirements.

The applicant submits missing requirements in writing to the Authority within **fifteen (15) working days** upon receiving the notification of screening results. The applicant may request for extension before deadline. Incomplete CTAs (<70%) will be subjected to resubmission.

II.2 Review of Clinical Trial Applications

The accepted CTAs are subject to the full review of protocol and its supplementary documents including investigational product dossier and IB, in order to assess the quality, safety and efficacy of the investigational product.

In addition, the Authority undertakes the detailed review of non-clinical data, quality data (Chemistry, Manufacturing and Control), clinical, statistical and administrative data using the review templates prescribed in the corresponding standard operating procedures (SOP) and electronic system.

The clinical trial application is subjected to the first and second reviews to increase transparency and quality assurance.

While applying rolling assessment of benefit-risk, the review of clinical trial applications is undertaken using the same set of criteria regardless of the applicant. The review prioritization follows the first-in first-out rule (FIFO), except for clinical trials that are conducted in public health emergencies or any other unmet medical needs which may be considered for expedited review.

Generally, the initial review of CTAs may result in queries or additional information that needs to be addressed by the applicant. In this situation a communication documenting all deficiencies in the application will be issued to the applicant.

II.3 Timelines for review of Clinical Trial Applications

The routine review and approval of new clinical trial application does not exceed sixty (60) working days and thirty (30) working days for clinical trial amendment applications.

In the event of public health emergencies, the clinical trial review process shall be conducted and provide approval of clinical trial application in 10 working days for products already registered for other indications and 15 working days for novel products.

The submission of clinical trial application response to queries or clarifications from the applicant shall not exceed thirty (30) working days unless she/he requests for extension in writing before deadline. Additional (30) working days for justified extension or reminder for submission of response to queries shall be allowed to facilitate engagement between involved parties. Failure to comply with prescribed timelines will bear the rejection of the application.

These timelines shall not include the time taken by the applicant to respond to any request for additional information or clarification from the Authority. A stop-clock mechanism shall thus apply each time the Rwanda FDA requests for additional information. This will help to monitor timelines for each application from the date application to the final approval.

The internal tracking system and a standards operating procedure shall be put in place to monitor compliance with above prescribed timelines for review and approval of clinical trial applications.

II.4 Types of clinical trial reviews

CTAs submitted to the Rwanda FDA may be subject to any of the four (4) types of reviews depending on the applicable criteria.

II.4.1 Routine review of Clinical Trial Applications

The routine review of CTAs is conducted according to the established procedures and timelines. This type of review applies to any type of investigational products based on available data depending on product development stage.

II.4.2 Non-routine reviews of clinical trial application

The non-routine review process is a pathway for accelerating the review and approval of clinical trial application by using reliance, fast-track or expedited decision-making (e.g., receipt, screening, evaluation, review, and authorization) under certain circumstances (e.g., public health emergencies).

a) Expert Reviews

The expert reviews of Clinical trials apply when the Authority hires/invites the external reviewers following the internal procedures depending on the complexity of clinical trial applications that require special expertise. The experts will sign a confidentiality agreement with the Authority to ensure the protection of the clinical trial information.

b) Joint Reviews

The joint reviews of Clinical Trial Applications are carried out jointly by the Rwanda FDA with other relevant regulatory bodies at national, regional or international level. The applications are reviewed by experts from each participating regulatory body and the coordination is done by a designated regulatory authority. Therefore, a regulatory decision will be taken at national level once all the requirements are fulfilled.

c) Reliance during review

In case Rwanda FDA has received the clinical trial application for the protocol that has been approved by other competent regulatory authorities, regional and/or international bodies, Rwanda FDA may rely on review reports or valid approval and consider the review of the country specific regulatory requirements for avoiding duplication of efforts or waste of resources in line with relevant reliance guidelines. Rwanda FDA reserves rights to request any additional information to ensure the safety and well-being of trial participant is protected.

d) Expedited Reviews

In case of public health emergencies or unmet medical needs, the Rwanda FDA may expedite the

review of clinical trials for medical products aiming at preventing or treating life-threatening diseases where there is no alternative therapy in line with relevant guidance for clinical trial application review during public health emergencies and unmet medical needs. In addition, this review can apply to products listed by WHO Emergency Use Assessment and Listing (EUAL) Procedure and African Vaccine Regulatory Forum (AVAREF) readiness plan.

The review of the application for compassionate use of unauthorized investigational products shall be based on the requirements set out in latest version of AVAREF Guidance and Considerations on Compassionate Use Access.

e) Rolling review of benefit-risk

A rolling review is one of the regulatory tools that Rwanda FDA uses to speed up the assessment of a promising medicine or vaccine during public health emergencies and unmet medical needs.
In this case, information and data are submitted as they become available, and allow for review of these data in parallel with clinical trial activities still ongoing. To apply rolling assessment of benefit-risk, the available data shall include nonclinical, quality and clinical Phase II data that demonstrate promising evidence of safety and efficacy. Furthermore, sponsors must submit a plan giving the anticipated timelines for submitting additional data from completed studies as part of the initial application.

II.5 Review of additional data & updates on clinical Applications

The sponsor or principal investigator is responsible for preparing responses to queries raised by the Rwanda FDA during the review process of CTAs. Any new information available for the investigational product such as adverse effects, updates to the Investigator Brochure, changes in formulation or manufacturing for the active ingredients or finished products shall be notified to the Authority. However, when the new data requires significant changes of the clinical trial design, investigational product or control or the overall benefit-risk balance to the trial participants and quality of data, Rwanda FDA will proceed to the rejection of the existing application and the sponsor or principal investigator shall submit a new clinical trial application.

Rwanda FDA reviews the query responses/clarifications provided and if the information is satisfactory, the CTAs approval process are initiated. If the applicant provides non - satisfactory query responses for two successive times for the same requested information, the application shall be rejected.

II.6 Review of quality, non-clinical and clinical data

The Rwanda FDA reviews quality, non-clinical and clinical data submitted to support clinical trial application. Reviewers shall pay attention on potential safety issues which may influence eventual clinical application of the investigational products.

II.6.1 Quality Review of investigational product (s)

The Rwanda FDA reviews the quality part of the investigational products including placebo/active control to ensure that the Chemistry, Manufacturing and Control (CMC) is

consistently followed from active substance to finished products.

The reviewers shall verify the validity and authenticity of GMP certificate or confirmation of GMP compliance or GMP inspection report issued, by other regulatory authorities. In order to accept the GMP compliance, the Authority may rely on valid and authentic GMP certificate, confirmation or GMP inspection report issued by:

a) Stringent Regulatory Authorities/WHO listed authorities;

b) Competent Authority of countries that are standing PIC/s members;

c) World Health Organization (WHO) prequalification program;

d) Authorities operating at least at maturity level 3(ML3);

e) Competent Authority that has a recognition agreement with the Authority;

f) EAC Joint GMP inspection procedure.

In case the investigational product is manufactured in a country whose GMP control system is not recognized by Rwanda FDA, but the clinical trial has been authorized by one of the stated bodies a, b, c, d, e, and f, the decision from that body may be considered.

The information related to investigational product quality will be reviewed using the review templates prescribed in the corresponding standard operating procedures (SOP) and electronic system for Investigational Product Quality Review adopted from latest version of the AVAREF tools.

II.6.2 Review of non-clinical data

The review of non-clinical data will be performed focusing on available pre-clinical data, pharmacology data (primary and secondary pharmacodynamics, safety pharmacology), pharmacokinetics data, toxicology data and other considerations such as Good clinical and laboratory practices.
The reviewer will ensure that non-clinical aspects of the IB or SmPC are in line with the SmPC of the reference product. In addition, the reviewer (s) will provide the conclusion by using one of the following two options:

a) Given that the pharmacodynamics, pharmacokinetic and toxicological properties of investigational products <ACTIVE SUBSTANCE> are well known and the applicant has provided additional studies (where applicable), therefore further studies are not required.
b) The reviewer(s) considers that the non-clinical overview on pre-clinical pharmacology, pharmacokinetics and toxicology is not adequate.

If the second option is chosen, the reviewer shall provide a detailed description of the missing information and its impact. This should then be translated into the draft list of questions.

The review of non-clinical data shall be made using the template for review of non-clinical data

adopted from latest version of the AVAREF tools. This template is prescribed in the corresponding standard operating procedures (SOP) and electronic system for non-clinical data review**.**

II.6.3 Review of Clinical Data

During the review of clinical trial applications, Rwanda FDA shall raise any concerns about compliance with GCP or related regulatory and ethical requirements (data accuracy or protocol compliance and compliance with ethical aspects) using the template for review of clinical data. The following will be taken into consideration where applicable:

a) Product Development Rationale

b) Overview of Biopharmaceutics (If applicable)

c) Overview of Clinical Pharmacology

d) Overview of Efficacy (If applicable)

e) Overview of Safety

f) Benefits and Risks Conclusions

For clinical investigations on medical devices, In vitro-Diagnostics and softwares, the reviewer will verify consistency and compliance with international standards and regulations.

The review of clinical data shall be conducted using the template for clinical data review as it has been adopted from latest version of the AVAREF tools. This template is prescribed in the corresponding standard operating procedures (SOP) and electronic system for clinical data review**.**

II.7 Statistical Review of Clinical trial application

Rwanda FDA reviews the type of design (controlled, uncontrolled), randomization, blinding, sample size determination, trial power and level of significance.

The primary and secondary endpoints will be reviewed to ensure that they are capable of providing the most clinically relevant and convincing evidence directly related to the primary objective of the trial. The selection of the primary objective should reflect the accepted norms and standards in the relevant field of research.

The reviewer shall verify all technical details and principles guiding the methodology for data collection and analysis described in the submitted statistical analysis plan. Consistency with the protocol shall be evaluated focusing on detailed procedures for executing the statistical analysis of the primary and secondary endpoints and other data.

The review of statistical data shall be conducted using the template for statistical review as it has been adopted from latest version of the AVAREF tools. This template is prescribed in the corresponding standard operating procedures (SOP) and electronic system for statistical review**.**

II.8 General review report for Clinical Trial Applications

The first and second reviews of CTAs will generate a compiled review report which shall include administrative and scientific details as well as other relevant information on the different modules of the application. After review, the compiled review report will be presented and discussed during the Clinical Trial Technical Committee (CTTC) to make a recommendation for final regulatory decision.

CHAPTER III: REVIEW OF AMENDMENTS AND RENEWAL OF CLINICAL TRIAL

Rwanda FDA shall review the substantial amendment and renewal applications for approval or rejection. In the event that these applications meet regulatory requirements, Rwanda FDA shall issue new certificates. The review shall depend on requirements for amendments or renewals as set out in the guidelines for Clinical Trial Applications in Rwanda.

Rwanda FDA shall review and approve any amendments before being implemented unless it is an urgent safety measure for trial participants. The urgent amendment shall be notified within 10 working days for approval to the Rwanda FDA thereafter. The list of amendments and necessary required documents prior to the approval of the amendment are detailed in the Guidelines on Clinical Trial Applications in Rwanda. Rwanda FDA will compare the new change to the previously submitted information in the protocol. Rwanda FDA reviews the amended part of the protocol and/or its supplementary documents using the template for review of amendments.

Rwanda FDA shall review the renewal application against the requirements of renewal as stipulated in the guidelines of CTA, but also taking into account absence of harm to the trial participants in concordance with progress report and the approved protocol.

CHAPTER IV: CLINICAL TRIAL APPROVAL PROCESS

Upon successful review and approval of a clinical trial application, Rwanda FDA issues a Clinical Trial Approval Certificate (CTAC) with specific number and applicable conditions for compliance on the attachment as prescribed. The CTAC will have the following information: protocol title, protocol number and version if applicable, name (s) of investigational product (s) including placebo, name (s) of investigator(s), name (s) of sponsor (s), name (s) of trial sites, name of Contract Research Organization (CRO) if applicable, date of issuance and expiration date, name and signature of the Director General of the Rwanda FDA.

For renewal, Rwanda FDA issues approval certificate of renewal with new validity and reference number and keep the name of the initial CTAC. In the case of amendment, Rwanda FDA shall keep the same CTAC validity and issue certificate with new reference number.

When the sponsor/PI has not initiated the clinical trial after approval, he/she is required to communicate in writing within ninety (90) calendar days. Failure to abide by the aforementioned compliance shall result to temporal CTAC suspension by the Rwanda FDA until its expiration unless the sponsor/PI requests for reinstatement.

IV.1 Clinical trial registration

Rwanda FDA will establish, maintain and publish a register or database of approved, rejected clinical trial applications. The information required for register of clinical trials will include the following:

a) Application reference number

b) Protocol title

c) Sponsor

d) Principal investigator

e) Investigational product (s) name and category

f) Clinical trial site

g) Clinical Trial Phase

h) Targeted number of trial participant

i) Clinical trial duration

j) Status of the trial

k) Certificate number and validity

IV.2 Publication and maintenance of clinical trial register

Rwanda FDA ensures that the register has relevant information on approved, rejected clinical trial applications. The outcomes of completed trials, a list and respective reasons of suspended and/or terminated clinical trials will be published and updated on quarterly basis.

IV.3 Publication of clinical trials evaluation reports

The summaries of evaluation reports of both approved and rejected clinical trials shall be generated and published on Rwanda FDA website. The content, format and information included in the summary evaluation reports will be established according to the relevant procedures in place. Database shall be updated within sixty (60) working days after clinical trial approval.

CHAPTER V: POST TRIAL PROTOCOL REVIEW

Rwanda FDA shall review the post-trial access protocol of completed clinical trials to ensure equitable access of the treatment for the safety and welfare of trial participants until the product is commercially available. Upon satisfactory information, Rwanda FDA shall issue a notification letter for Post-Trial Access. The decision to grant post-trial access will depend on the participant's medical need, including the availability of alternative therapies and review of what is known

about the benefits and risks of the investigational product. Rwanda FDA may consider granting post-trial access even when the trial was discontinued or had negative outcomes, as long as the trial was not stopped for major safety issues. The criteria include but are not limited to the following:

a) Participant must have a serious or life-threatening condition

b) The treating physician and/or investigator has determined that post-trial access is the best medical option for the patient;

c) Investigational product is not yet approved/authorized in that indication;

d) The participant must have been part of the trial in which the investigational product was administered;

e) The administration of the product must have resulted in clinical benefit to the individual based on the investigator's assessment of the participant's response to the intervention and the risks of using the investigational product at the time of the decision;

f) Sponsor must accept and have an adequate supply of investigational products.

ENDORSEMENT OF THE GUIDELINES

	Prepared by	**Checked by**		**Approved by**
Title	**Division manager**	**Head of Department**	**QMS Division Manager**	**Director General**
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